

## Readoption Review

### Examination of Infants for Disorders 410 IAC 3-3

IC 4-22-2.5-3.1(c) requires an agency to conduct a review to consider whether there are alternative methods of achieving the purpose of the rule that are less costly or less intrusive, or that would minimize the economic impact of the proposed rule on small business.

#### **Description of Rule:**

The Indiana State Department of Health (ISDH) has responsibility for the regulation and administration of the Newborn Screening program under IC 16-41-17. In 1996, the Indiana General Assembly enacted IC 4-22-2.5, to establish automatic expiration of any rule in effect for more than seven years, and to create a streamlined method for readoption of such rules without change. In accordance with IC 4-22-2.5, 410 IAC 3-3 must be readopted if it is to remain in effect. IC 3-3 are the rules the agency uses to administer the Newborn Screening program including requirements for screening, conditions included in the screening, laboratory and physician responsibilities, follow up requirements, and funding mechanisms.

#### **Readoption Analysis:**

**1) Is there a continued need for this rule?**

IC 16-41-17 establishes the Newborn Screening program and requires the ISDH to adopt rules to administer the program. The statute IC 16-41-17 remains in effect so there is a continued need for the rule to provide specific administrative procedures for the program.

**2) What is the nature of any complaints or comments received from the public, including small business, concerning the rule or the implementation of the rule by the agency?**

There is no record of any complaints or comments received from the public or small business concerning this rule or the implementation of this rule by the ISDH, since its most recent update in 2001.

**3) Examine the complexity of the rule, including difficulties encountered by the agency in administering the rule and small businesses in complying with the rule.**

There is a continuing challenge in providing follow up to identify Newborn Screening cases in situations where the child does not have an ongoing responsible pediatrician. In many cases, the responsible physician submitting the Newborn Screening specimen is the hospital staff obstetrician who does not have an ongoing relationship with the child or their parents.

**4) To what extent does the rule overlap, duplicate, or conflict with other federal, state, or local laws, rules, regulations, or ordinances?**

This rule does not overlap, duplicate, or conflict with any other federal, state, or local laws, rules, regulations, or ordinances. This rule does support the requirements of Title V of the Social Security Act.

**5) When was the last time the rule was reviewed under this section or otherwise evaluated by the agency, and the degree to which technology, economic conditions, or other factors have changed in the area affected by this rule since that time?**

This rule was last reviewed and amended in 2001 to revise the list of designated conditions for screening.

13 April, 2007